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EXAMINER	
LAMM, MARINA	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,069	CAWTHON, GARRET D.	
	Examiner	Art Unit	
	Marina Lamm	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-53 and 57-86* is/are pending in the application.

4a) Of the above claim(s) *61-73 and 83-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-53, 57-60, 74-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the amendment filed 5/30/06. Claims pending are 39-53 and 57-86. Claims 39, 51, 58 and 59 have been amended. Claims 54-56 have been cancelled. Claims 74-86 have been newly added. Claims 61-73 remain withdrawn from consideration as directed to non-elected invention. Claims 83-86 have been withdrawn from consideration as directed to an invention non-elected by original presentation. See below.

Election/Restrictions

1. Newly submitted claims 83-86 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the invention claimed in new Claims 83-86 and the originally claimed invention are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the new claims 83-86 do not require the presence of any of the specific composition ingredients recited in the original claims. The subcombination has separate utility such as diaper rash treatment.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

prosecution on the merits. Accordingly, claims 83-86 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 39-53, 57-60 and 74-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 39, 58 and 59, as amended introduce new matter as they use the phrase "substantially free from propellant gases". There is no support in the specification for the employment of this phrase in the claims. The limitation "skin treatment area substantially free from propellant gases" was not described in the application as filed, and persons skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. While the instant specification describes applying the composition of the invention to the areas of skin affected with skin rashes and irritation, it does not mention that the skin treatment areas are "substantially free from propellant gases" as claimed in Claims 39 and 59, or the

treatment composition is "substantially free from propellant gases" as claimed in Claim 58 herein. The limitation "propellant gases" encompasses a large group of compounds, including carbon dioxide and nitrous oxide, which can be used as "propellant gases", but are also normally present in the air. Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor has possession of the subject matter of the amendment at the time of filing of the instant application. The instant claims now recite the limitation which was not clearly disclosed in the specification as filed, and now changes the scope of the instant disclosure as filed. Such limitation recited in the present claims, which did not appear in the specification, as filed, introduces a new concept and violates the description requirement of the first paragraph of 35 U.S.C. 112. Applicant is required to cancel the new matter in the response to this Office action. Alternatively, the Applicant is invited to point out to the parts of the specification which provide sufficient written support for the above-mentioned range. See MPEP 714.02 and 2163.06.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 39-53, 57, 59, 60, 74-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39 and 57, as amended, are viewed as indefinite because they recite the limitation "skin treatment area substantially free from propellant gases". It is unclear

what exactly this phrase mean and how one would know whether or not the skin treatment area is free of such gases.

Claims 76, 79 and 82 (new) are viewed as indefinite because they recite the limitation "leave a relatively drier coating on the skin treatment area". The term "relatively drier coating" is a relative term which renders the claim indefinite. The term "drier" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Claims 77 and 78 recite the limitation "the atomizing spray delivery mechanism". There is insufficient antecedent basis for this limitation in the claims since Claim 58, from which Claims 77 and 78 depend, do not recite such limitation.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 39-50 and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (EP 191 128) in view of Moss (US 4,816,254) and Mulder (US 5,536,502), all of record.

Adams et al. teach diaper rash aerosol-type composition containing about 70% of water, jojoba oil and macadamia oil. See pp. 5-7, Examples 5 and 6. The recitation of viscosity that is "sufficiently low to allow the composition to be atomized" is inherent in the reference because the reference teaches compositions in the sprayable form.

With respect to the limitation "composition substantially free from propellant gases" in Claim 58, as amended, the compositions exemplified in Adams et al. do not contain any propellant gases. See Examples. Although, Adams et al. is silent with respect to the claimed "container and an atomizing spray delivery mechanism affixed to the container", such limitations are implicit in the reference since compositions are provided in containers and the teaching of "aerosol-type" composition indicates that the composition is delivered via spraying, i.e. using some spray delivery mechanism. The Adams et al. reference does not teach the component (2) of the instant claims. However, Moss teaches that severe cases of diaper rash may result in complications such as decubitus ulcer, wherein skin breaks down. See col. 1, lines 21-27. Moss suggests that is desirable to treat diaper rash and decubitus ulcer simultaneously. See col. 1, lines 33-47. The compositions of Moss contain zinc oxide, which has antiseptic activity, and cod liver oil, which provides the skin with vitamins A and D and promotes rapid, scar-free healing. See col. 2, lines 48-55; col. 3, lines 35-47. Further, Mulder teaches using zinc oxide topical protectant in spray-on liquid compositions for the treatment of skin lesions (e.g. skin injury and skin tears) in order to promote healing. See col. 1, lines 15-21; col. 2, lines 42-43; Example 1. Mulder also teaches using petrolatum and lanolin as emollients in topical compositions for their soothing action by lubricating injured skin. See col. 4, lines 50-56. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol-type diaper rash compositions of Adams et al. such that to use zinc oxide for its

art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain an antiseptic and wound healing effect as suggested by Moss and Mulder. One having ordinary skill in the art would have a reasonable expectation of success because Mulder shows how to incorporate zinc oxide into spray-on liquid compositions. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the diaper rash compositions of Adams et al. such that to use cod liver oil, lanolin and petrolatum. One having ordinary skill in the art would have been motivated to do this to obtain rapid, scar-free healing and soothing action of the composition as suggested by Moss and Mulder. With respect to Claims 41-43 and 60, which recite an average particle size of zinc oxide, neither reference explicitly teaches the claimed size. However, the determination of optimal or workable size of zinc oxide by routine experimentation is obvious absent showing of criticality of the claimed size. One having ordinary skill in the art would have been motivated to do this to obtain the desired skin protectant and/or aesthetic properties of the composition.

8. Claims 41-43 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (EP 191 128) in view of Moss (US 4,816,254) and Mulder (US 5,536,502), and further in view of Boussouira et al. (US 6,103,247), all of record.

Adams et al. in view of Moss and Mulder applied as above. Neither reference explicitly teaches the zinc oxide particle size of the instant claims. However, Boussouira et al. teach using transparent zinc oxide having an average diameter of 1-500 nm in

cosmetic composition because of its aesthetic appeal. See col. 5, lines 31-42. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the diaper rash compositions of Adams et al. in view of Moss and Mulder such that to use transparent zinc oxide having an average diameter of 1-500 nm. One having ordinary skill in the art would have been motivated to do this to obtain aesthetically pleasing compositions as suggested by Boussouira et al.

9. Claims 39, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (EP 191 128) in view of Neubourg (WO 99/08649 as translated by US 6,423,323), all of record.

Adams et al. applied as above. Further, Adams et al. teach using "herbs tea" in their diaper rash formulations. Neither reference teaches calendula, chamomile or comfrey extracts of the instant claims. However, Neubourg teaches using calendula and chamomile extracts in topical diaper rash treatment compositions. See col. 5, lines 15-24. Chamomile is used for its soothing properties. See col. 5, lines 11-14. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of Adams et al. such that to use calendula and/or chamomile extracts. One having ordinary skill in the art would have been motivated to do this to obtain soothing and diaper rash-treating properties as suggested by Neubourg.

10. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (EP 191 128) in view of Neubourg (WO 99/08649 as translated by US 6,423,323) as applied to Claim 51 above and further in view of Moss (US 4,816,254), all of record.

Adams et al. in view of Neubourg applied as above. Neither reference teaches the ingredients of the instant claim. However, Moss teaches compositions for the treatment of skin irritations such as diaper rash containing cod liver oil, which provides the skin with vitamins A and D and promotes rapid, scar-free healing. See col. 2, lines 48-55; col. 3, lines 35-47. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the compositions of Adams et al. in view of Neubourg such that to use cod liver oil. One having ordinary skill in the art would have been motivated to do this to obtain rapid, scar-free healing action as suggested by Moss.

11. Claims 76, 79 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (EP 191 128) in view of Clark et al. (US 6,103,245), of record.

Adams et al. teach diaper rash aerosol-type compositions as discussed above. The reference does not teach the claimed volatile compound. However, Clark et al. teach using volatile silicone compounds such as cyclomethicone, in topical barrier compositions suitable for providing non-irritating protective coating for incontinent patients and for managing diaper rash. See col. 2, lines 1-7, 61-67; col. 3, lines 11-14; col. 4, lines 55-58. Cyclomethicone provides "excellent application and spreading characteristics and has an excellent tactile feel". Cyclomethicone "rapidly evaporates

without cooling the skin." See col. 5, lines 62-67. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Adams et al. such that to use cyclomethicone. One having ordinary skill in the art would have been motivated to do this to obtain non-irritating protective skin coating as well as good spreadability and skin feel of the composition as suggested by Clark et al.

12. Claims 39, 58, 59, 74, 75 and 77-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (EP 191 128) in view of Moss (US 4,816,254) and Mulder (US 5,536,502) and further in view of Hartung et al. (US 5,436,007), of record.

Adams et al. in view of Moss and Mulder applied as above. While teaching "aerosol-type" diaper rash formulations, Adams et al. do not explicitly teach the claimed atomizing spray delivery mechanism such as pump spray dispenser. However, Hartung et al. teach applying diaper rash lotion by means of "a spray from an aerosol or pump dispenser" as well as by other means. See col. 5, lines 10-13; col. 13, lines 37-41. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the sprayable diaper rash treatment composition of Adams et al. in view of Moss and Mulder by means of a pump dispenser with a reasonable expectation of achieving the same skin protecting and healing effect as set forth in the Adams et al. reference. One having ordinary skill in the art would have been motivated to do this because the treatment composition can be sprayed directly onto the baby's skin as suggested by Hartung et al.

Response to Declarations

13. The declaration of Shishir Shah under 37 CFR 1.132 filed 5/30/06 is insufficient to overcome the rejection of the instant claims based upon Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Moss (US 4,816,254) and Mulder (US 5,536,502) as set forth in the last Office action because: the declaration is a mere statement of the opinion and does not presented any experimental data in support of that opinion. Therefore, it is given little weight.

14. The declaration of Dean O. Harper under 37 CFR 1.132 filed 5/30/06 is insufficient to overcome the rejection of the instant claims based upon Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Moss (US 4,816,254) and Mulder (US 5,536,502) as set forth in the last Office action because: the declaration is a mere statement of the opinion and does not presented any experimental data in support of that opinion. Therefore, it is given little weight.

15. The declaration of Garret D. Cawthon under 37 CFR 1.132 filed 5/30/06 is insufficient to overcome the rejection of the instant claims based upon Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Moss (US 4,816,254) and Mulder (US 5,536,502) as set forth in the last Office action for the following reasons: (1) the results demonstrated in the declaration are not commensurate in scope with the instant claims. More specifically, the Applicant tested compositions containing specific ingredients present at the specific concentrations, while the instant claims (with the exception of Claim 47) do not recite any concentrations and do not recite any specific

formulations; (2) the Applicant compared the composition of Mulder (US 5,536,502) with five compositions within the scope of the instant claims and found that the composition of Mulder did not pass the sprayability test because it "had a consistency that resembled pancake batter at 50^0C and a thick paste at room temperature", but passed "the run-off resistance test". First, it is noted that the Mulder patent is not the closest prior art and was used as a secondary reference to supplement the teachings of Adams et al. and Moss et al. Second, Mulder clearly and explicitly teaches that the composition prepared according to the formula in Table 1 "is a **low viscosity**, shelf-stable emulsion of pH 6.5 that **can be applied to a wound site through the use of a conventional spray bottle apparatus**". "The **viscosity of the medicament is low enough to permit spray application, yet high enough to prevent substantial free liquid runoff subsequent to application.**" See col. 5, line 63 – col. 6, line 7. (Emphasis added). Since Mulder does not mention heating the medicament to 50^0C before applying it to the wound, and such step would be contrary to both common sense and good medical practice, it is reasonable to assume that the composition of Mulder is used at the room temperature. Since the Applicant's finding appears to be inconsistent with the reference's clear and explicit teaching, and the issued US patents enjoy the presumption of validity, the Applicant's experimental data is not found persuasive.

Response to Arguments

16. Upon reconsideration and in view of the amendment to the claims, the rejection over Gebhart reference has been withdrawn. However, the instant amendment introduces new matter to the claims as discussed above. Upon cancellation of the new matter, the rejection over Gebhart will be reinstated. At this point, the Applicant's arguments with respect to the Gebhart reference are moot.

17. Applicant's arguments filed 5/30/06 have been fully considered but they are not persuasive.

The Declarations submitted by the Applicant have been addressed above and will not be further discussed in this section.

The Applicant argues that the Adams et al. reference "describes aerosol compositions that uses [sic] propellant gases entrained therein for delivery of the compositions". See p. 17 of the reply. (Emphasis in original). In response, Adams et al. exemplify two "diaper rash aerosol type" formulations which do not contain any propellant gases. See pp. 5-7, Examples 5 and 6 of Adams et al. Contrary to the Applicant's assertion, there is no general or specific teaching of propellant gases in Adams et al.

With respect to the Mulder reference, the Applicant argues "[t]he description in the Mulder reference of the composition set forth in Table 1, however, also suggests that this composition would not be able to form a coating that 'does not run off the skin treatment area,' as recited in Dr. Cawthon's pending claims." See p. 20 of the reply. In

response, Mulder clearly and explicitly teaches that the composition prepared according to the formula in Table 1 does not run off. "The **viscosity of the medicament is low enough to permit spray application, yet high enough to prevent substantial free liquid runoff subsequent to application**." See col. 5, line 63 – col. 6, line 7. (Emphasis added). Further, the Applicant's own Declaration demonstrated that the composition in Table 1 of Mulder "satisfied the run-off resistance test." See p. 9, first full paragraph.

With respect to the Applicant's arguments that "the Mulder reference is nonanalogous art" and "Mulder is not in the field of applicant's endeavor", it is noted that there are two separate tests to define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved. *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986); see also *In re Wood*, 599 F.2d 1032, 1036 (CCPA 1979). The "field of endeavor" test for analogous art requires the PTO to determine the appropriate field of endeavor by reference to explanations of the invention's subject matter in the patent application, including the embodiments, function, and structure of the claimed invention. *See Wood*, 599 F.2d at 1036 (confining the field of endeavor to the scope explicitly specified in the background of the invention); *see also Deminski*, 796 F.2d at 442 (determining that the cited references were within the same field of endeavor where they "have

essentially the *same function and structure*"). In this case, both tests would be satisfied for the following reasons: 1) the Mulder reference is within the field of the inventor's endeavor because the compositions of Mulder "have essentially the same function and structure", i.e. they are skin healing compositions, sprayable, contain the claimed ingredients; and 2) the Mulder reference is reasonably pertinent to the particular problem with which the inventor is involved, i.e. healing of skin lesions.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm, M.S., J.D.
Patent Examiner
8/6/06

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SUPERVISORY PATENT EXAMINER